

Final Supporting Statement for
Proposed NRC "Nuclear Material Events Database (NMED)"
for the Collection of Event Report, Response, Analyses, and Follow-up Data on Events
Involving the Use of Atomic Energy Act (AEA) Radioactive Byproduct Material
(3150-0178)
Revision/Extension

Description of the Information Collection

The title has been changed to more accurately reflect the scope of the information collection burden. The NRC proposes to continue the automated collection of Agreement State licensee data on the occurrence of incidents and events involving the use of radioactive byproduct material, such as medical misadministrations, radiation overexposures, environmental releases, contamination, leaking sources, lost sources, equipment failure, etc. This information is submitted to the Agreement States by their licensees through Agreement State regulations that are compatible to NRC regulations, and that require the reporting of incidents and events involving the use of radioactive byproduct materials. In addition, NRC requests that the Agreement States report by telephone significant events that could pose a significant health and safety hazard to NRC within the next working day of notification by their licensee. (In accordance with established regulatory requirements, Agreement State licensees report significant events to the Agreement State within 24 hours.) These and other radioactive material events will be reported on a monthly basis using the automated system. Agreement States may also choose to submit reports in written form by using a copy of the NMED data screen. NRC is requesting that the Agreement States provide information on the initial notification, response actions, and follow-up investigations.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information.

The Commission is directed under the Atomic Energy Act of 1954 ("the Act") Sections 274, Sec. 2, Findings, Paragraphs D and E, to protect the public against the hazards of radiation. The Commission is authorized to study, inspect, and monitor, as necessary, to protect health and minimize any danger to life or property. In 1959, Section 274 of the Atomic Energy Act was enacted to spell out a State's role and to provide a statutory basis under which the Federal government could relinquish to the States portions of its regulatory authority. The 1959 amendments made it possible for the State to license and regulate byproduct, source, and small quantities of special nuclear material. The mechanism for the transfer of NRC's authority to a State is an Agreement signed by the Governor of the State and the Chairman of NRC. These States are known as Agreement States. Pursuant to the 1954 "Act" and the Energy Reorganization Act of 1974, as amended, the NRC investigates significant events and abnormal occurrences in licensed facilities. The Energy Reorganization Act requires NRC to provide to Congress on an annual basis, information on significant events that meet the abnormal occurrence criteria. Pursuant to Section 274j of the Act, the Commission evaluates Agreement State

programs to ensure that each Agreement State has a program that is compatible with NRC's program and to ensure that the State's regulatory program is adequate to protect the public health and safety. In addition, Section 274g of the Act requires NRC to cooperate with Agreement States in the formulation of standards for protection against hazards of radiation. The information from incidents and events involving the use of radioactive material at medical, industrial and research facilities located in the Agreement States, is invaluable in assessing actual Agreement State regulatory experience. The analyses of events provides valuable information and may result in the identification and review of safety concerns.

Responsibility for regulating the 22,000 specifically licensed users of radioactive materials is shared between NRC and the 31 Agreement States. A State may regulate from as few as 100 licenses to over 2,000 licenses. Agreement State material licensees include about 4,500 medical licensees and about 12,500 other nonreactor licensees. Approximately 70 percent of the licensed users of radioactive material are regulated by the Agreement States. Therefore, we could expect a representative proportion of nuclear material event report data, including medical events, from Agreement State licensees.

We are requesting a continuation of the collection of this information in a standardized format, through electronic transmission into the Nuclear Material Events Database (NMED). The automated system was designed to improve the technical information content of event reports, increase consistency, improve ease of access and retrieval of event information, and reduce duplication of effort in processing and rekeying information by all parties involved. The automated system has resulted in an improvement in the technical content of reports. NMED has become a valuable analytical and statistical support tool. All events will be reported on a monthly basis, primarily using the automated system. The NMED data entry elements were expanded in 1997 to respond to General Accounting Office and Congressional recommendations to provide a complete national set of data that is adequate to perform long-term trend analyses of what occurred, direct and indirect causes, possible precursors, identify any site specific or generic issues and any effects (long and short-term) as a result of the event, as well as the health and safety significance.

In addition, events that could pose a significant health and safety hazard will be reported by the Agreement States to the NRC Operations Center, within the next working day of notification by their licensee. (In accordance with established regulatory requirements, licensees report significant events to an Agreement State within 24 hours.)

2. Agency Use of the Information

- a. The NRC collection of Agreement State licensee data on incidents and events involving the use of radioactive byproduct material, such as medical misadministrations, radiation exposures, environmental releases, contamination, leaking sources, lost sources, equipment failure, etc., significantly aids in understanding material events and identifying actions

necessary to improve the effectiveness of NRC and Agreement State regulatory programs. Information is collected and maintained on preliminary initial notification information, and event response, analyses and follow-up activities. Some significant events (reportable within 24 hours or less) may meet the criteria for an abnormal occurrence. NRC is required to report abnormal occurrences to Congress on an annual basis.

- b. Agreement State licensees report the occurrence of events involving the use of radioactive byproduct material to Agreement State regulators (within 24 hours or 30-60 days) in accordance with Agreement State reporting requirements. These reporting requirements are compatible to the U.S. Code of Federal Regulations (10 CFR). As a matter of compatibility, the Agreement States provide copies of licensee event reports to NRC. States are requested to provide event reports within one month or 30 days of receipt from their licensee. Information on significant events (reportable within 24 hours or less) is reported by the Agreement States to the NRC Headquarters Operations Center within the next working day after notification from their Agreement State licensee.
- c. Significant events, reported to the NRC Headquarters Operations Center, are monitored by NRC. NRC monitors the Agreement State event response activities, and stands ready to offer Federal assistance. NRC is the official lead Federal agency (LFA) for radiological emergencies involving AEA material. As the LFA, NRC is responsible for coordination of the Federal response, including assistance from NRC or other agencies, e.g., FEMA, DOE, etc., as requested by the States. Agreement State staff may be requested to brief NRC managers on the status of significant event response and investigations.
- d. NRC conducts an assessment of the periodic collection of event data provided from the individual Agreement States, both individually and collectively. The analyses of the initial notification, response actions, follow-up investigative information, and close-out of material events, provides valuable information and may result in the identification and review of safety concerns that could have public health and safety significance. NRC reviews radiation safety incident reports and assesses the information against other similar operating experiences at licensed facilities. These assessments can provide important information to NRC, Agreement States, and other material licensees regarding generic or recurring problems, as well as safe operational details and procedures. Specific task forces or working groups may be established to analyze problems and provide lessons learned. These assessments may also identify generic implications which would indicate a need for NRC to assess any changes necessary to nuclear material policies or regulations. This information is also used during formal periodic reviews of an Agreement State radiation control program to assess the adequacy of their programs. The NRC also provides feedback to industry, the regulated community and others, in the form of technical reports, safety notices, training programs, video tapes on medical and industrial safety

training, etc., on lessons learned in order to improve safety. Statistical data analysis information, generated from the NMED database, has become a valuable support tool in our continued efforts to identify and address specific and generic safety-related issues.

3. Reduction of Burden Through Information Technology

NRC incorporates the regulatory reporting requirements and risk factors into the event reporting process, for timely event notification, monitoring event response activities, and the collection and assessment of follow-up investigative information. NRC has worked with and continues to work with the Agreement States to develop and refine the NMED database system to provide the necessary information through the most efficient and cost effective method. The national electronic database system provides the Agreement States with online access to nuclear material event information from NRC and Agreement State licensees. The current percentage of information collected electronically is approximately 65. Attachment A contains a list of the fields or elements that would be used to collect medical misadministration and incident and event information.

4. Efforts to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found. There is no similar information available to the NRC. The information provided through the subject electronic database is not available from any other source other than Agreement States.

5. Effort to Reduce Small Business Burden

This information is requested only from Agreement State regulatory authorities.

6. Consequences to Federal Program or Policy Activities if the Collection is not Conducted or is Conducted Less Frequently

Collecting information on a less frequent basis could impact public health and safety, would greatly reduce the usefulness of the assessments of nuclear material events that have occurred in the Agreement States, and would impact our responsibility to report abnormal occurrences to the Congress and the public in a timely manner. NRC requests that Agreement States report by telephone information on events that could pose a significant health and safety hazard to the NRC Operations Center within the next working day of notification to the Agreement State by an Agreement State licensee. (Under established regulatory requirements, Agreement State licensees will report significant events to the Agreement State within 24 hours.) Additional follow-up information on significant events is requested to be provided as it is collected by the States. Some significant events meet the criteria of an abnormal occurrence and are included in NUREG-0090, the NRC annual abnormal occurrence report to Congress, required by the Energy Reorganization Act of 1974. Agreement States provide information on events that do not pose a significant health and safety hazard to NRC within one month or 30 days of receipt from their licensee.

7. Circumstances Which Justify Variation from OMB Guidelines

Information on events that could pose a significant health and safety hazard is requested from Agreement States, within the next working day of notification by their licensee so that NRC can identify immediately any health and safety hazard to the public, and offer assistance to the Agreement State in responding to the event. (Under established regulatory requirements these events will be reported by a licensee to the Agreement State within 24 hours or less.)

8. Consultations Outside the NRC

Opportunity for public comment was published in the *Federal Register* on March 28, 2000 (65 FR 16420). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Proprietary information is only generated in a small percentage of Agreement State collections. However, this information will be handled in accordance with NRC regulations in 10 CFR 2.790.

11. Justification for Sensitive Questions

No sensitive information is requested.

12. Estimated Burden and Burden Hour Cost

Agreement State Regulatory Authority: Through formal Agreements with the Governor of a State, the NRC relinquishes regulatory authority to the State. As the entity with regulatory authority, Agreement States, through regulations that are compatible to NRC regulations, require their licensees to report events and medical misadministrations involving the use of radioactive byproduct material. Additionally, as the entity with regulatory authority, the Agreement State radiation control program, generally under the State Department of Health, shoulders the responsibility and burden of collecting nuclear material event information from Agreement State licensees and reporting this information to NRC. Therefore, the Agreement State licensee's burden to report nuclear material event information to the Agreement State, and the Agreement State's burden to collect this information, exists absent NRC's request for Agreement State participation in the electronic reporting of medical misadministration and other incidents and events. The burden is covered in separate OMB approvals for licensee reporting and Agreement State review.

The information is collected as follows: Agreement State licensees report information to the State regulator and the States in turn will enter event information received from their licensees into a local version of "Nuclear Material Events Database (NMED)," on a monthly basis, including follow-up investigative

reports. They will electronically transmit the information to NRC. Some small Agreement State programs with less than 100 licensees may provide NMED event reports in written form using a hard copy of the NMED data screen. Events do not occur with any particular frequency; therefore, a particular State may report 3-4 events during one month and may not report any information for the following two months.

The estimated burden on the Agreement States is presented below.

- a. The staff estimates that Agreement State licensees report approximately 600 material events annually to the Agreement State regulators. The previous burden hours (725 hours) were based on limited experience and limited participation (1/3) or 33% of event reports received electronically, and one report per event. Although efforts continue to increase the technical quality of the information reported, we have found it necessary to contact the States for additional follow-up information to clearly understand the safety significance and any possible generic implications, for approximately 50% of the reported events. Based on experience, the staff estimates that the 600 material events result in the receipt of approximately 900 event reports (including follow-up reports). The States process material event information received from their licensee and enter and transmit the information electronically to NMED. Based on actual experience, increased electronic reporting (averaging 65%), additional follow-up investigative report information, and one additional Agreement State, the current estimates for the Agreement State to process and enter material event information received from their licensee into NMED average about 1.0 hour/report).

$$900 \text{ event reports} \times 1.0 \text{ hour} = 900 \text{ burden hours}$$

- b. In addition to the above, the Agreement States report by telephone to the NRC Operations Center, within the next working day of notification by their licensee, events that occur that could pose a significant health and safety hazard. Based on experience, the States may orally report ongoing response and follow-up activities from 1-4 times, based on the type of event and safety significance. An additional oral report may be presented before the NRC monthly management Operational Events Review Meeting. Therefore the following estimate reflects an increase from (.25 hours/report) to (1.5 hours/report) for significant events. Staff estimates that 30 of the 600 events rise to the level of significant events, each of which would require up to 1½ (1.5) additional hours to provide an initial oral report and follow-up safety assessment investigative information.

$$1.5 \text{ hours/rpts.} \times 30 \text{ significant rpts.} = 45 \text{ burden hours.}$$

$$\text{The total burden for Agreement States is } (900 + 45) = 945 \text{ hours.}$$

$$\text{The total cost for Agreement States is } (945 \times \$90) = \$85,050.$$

13. Estimate of Other Additional Costs

None

14. Estimated Annualized Cost to the Federal Government

The previous burden hours (240 hours) and cost estimates (\$31,050) were based on limited experience and limited participation (1/3) or 33% of event reports received electronically. The previous estimate also did not include NRC staff time involved in monitoring significant event response activities, and oral briefings presented by Agreement State staff on the status of their investigations. The previous estimate was also based on receipt of one report per event. Through experience, we have found that significant events can result in 2-4 follow-up event reports for one occurrence, a few less significant events result in 1-2 follow-up reports, with most of the more routine events (e.g. incinerator alarms as a result of low-level radioactive material—medical waste, abandoned material, etc.) resulting in only one initial report. Follow-up reports are provided when any new investigative results or findings have been identified by the State. Although efforts continue to increase participation in electronic reporting and the technical quality of the information reported, we have found it necessary to contact the States for additional follow-up information to clearly understand the safety significance and any possible generic implications, for approximately 45% of the reported events. Based on actual experience, increased electronic reporting (averaging 65%), and one additional Agreement State, the current estimate reflects the increased effort incurred by the government, contractor hours increased from 240 to 1080, and staff hours increased from 40 to 390.

Based on experience, the staff estimates the following annualized cost estimates to (1) review and assess material event notifications, (2) monitor significant event response activities, (3) review follow-up investigative reports, (4) conduct safety assessments and analyses of both individual and collective Agreement State event information, and (5) code and maintain the collection of event information in NMED.

- a. The staff estimates receipt of approximately 600 event reports and 300 follow-up investigative reports per year, totaling 900 actions. The NMED contractor performs coding (data sorting and manipulation), data entry, health physics completeness review of event reports, and requests for additional information, as necessary for the estimated 900 event reports (estimates include 1.20 hours per event report).

$$900 \text{ reports} \times 1.2 \text{ hour/report} = 1080 \text{ hours}$$

$$1080 \text{ Hours} \times \$80/\text{hour} = \$86,400 \text{ (professional effort)}$$

$$50 \text{ Hours} \times \$45/\text{hour} = \underline{2,250} \text{ (clerical effort)}$$

$$\begin{array}{r} \text{TOTAL COST:} \\ \text{(Contractor Cost)} \end{array} \quad \$88,650$$

- b. The staff estimates that event analysis for trends, patterns or generic implications, including requests for clarification, will incur approximately .25-.75 hours per event, averaging .50 hours.

.50 hour/event X 600 events = 300 hours
300 hours X \$143/hour = \$42,900 (Staff cost)

- c. The staff estimates the following additional annualized costs to the Federal government based on approximately 30 of the 600 events rising to the level of significant events (reportable within 24 hours or less) that pose or could pose a significant health and safety hazard. Staff estimates it would take approximately three hours for processing by the NRC Operations Center, and monitoring response and follow-up activities.

3 hours X 30 significant events = 90 staff hours
90 staff hours X \$143/hour = \$12,870 (Staff Cost)

TOTAL STAFF HOURS = 390 hrs. (300 hours + 90 hours)
TOTAL STAFF COST: \$42,900 + \$12,870 = \$55,770 (Staff Cost)
TOTAL NRC COST: \$88,650 + \$55,770 = \$144,420 (Contractor & Staff)

These costs are fully recovered through license fees charged to NRC licensees pursuant to 10 CFR Part 170 and/or 171.

15. Reason for Change in Burden or Cost

The burden is estimated to increase from 725 to 945 hours. Based on additional experience, prompt detailed follow-up information is necessary for safety significant events, to evaluate technical response actions and provide for Federal assistance, where necessary, to ensure public safety. The previous clearance did not include estimates for monitoring of State event response activities for significant events or processing follow-up report information. Greater technical detail, as defined in the U.S. Code of Federal Regulations (10 CFR) reporting requirements, is needed for all events in order to evaluate possible generic issues that could involve issues of adequate protection, substantial safety enhancements, or burden reduction. One new Agreement State has also been established since the last review. Also, the reporting of material event information is now mandatory under compatibility policy for Agreement States (June 30, 1997, Commission Staff Requirements Memorandum for SECY 97-054, Final Recommendations on Policy Statement and Implementing Procedures for: "Statement of Principles and Policy for the Agreement State Program" and "Policy Statement on Adequacy and Compatibility of Agreement State Programs.") This has resulted in increased participation by the Agreement States and an increase in the number of event reports received. As a result of the above information, the electronic reporting burden for Agreement States has increased to 945 burden hours. We also estimate a reduction in burden hours of .50-1.0 hour (averaging .75 hour) as a result of an increase in electronic reporting and a decrease in reporting in hard copy.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

Not applicable. The expiration date is displayed. The database software displays the OMB clearance, burden estimate, expiration date and public protection statement as required.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Attachment:
As stated

DATA ENTRY INFORMATION FOR NUCLEAR MATERIAL EVENTS DATABASE (NMED) EVENT REPORT INVOLVING USE OF NUCLEAR MATERIAL

ATTACHMENT A

The Nuclear Material Events Database (NMED) contains the official NRC collection of information on all non-commercial power reactor incidents and events, including medical misadministration, that are required to be reported by the regulated community of licensees to NRC and the Agreement States, through NRC and compatible Agreement State regulations. The following 2 page list contains the NMED data entry elements necessary to support the collection of consistent information in a standardized format for all nuclear material incidents and events. Many of the items require only one keystroke for entry. Information has been pre-coded into a master list. The user scrolls through a pick list to the appropriate item and makes a choice. The codes have been developed to provide standardization and consistency in information, ease of retrieval, and to provide a three or four keystroke entry for lengthy information.

GENERAL INFORMATION

(For all Events)

- A. ORIGINAL ITEM NO
(State ID\YR\No.)
- B. FOLLOW UP RPTS NO.
(01, 02, etc.)
- C. EVENT CLASS (Code)
- D. EVENT DATE
- E. DISCOVERY- DATE REPORTED TO STATE
- F. DATE OF THIS REPORT
- G. EVENT CAUSE (Code)
- H. LICENSEE NAME, CITY AND
STATE, ZIP CODE (Code)
- I. LICENSE NO.
- J. SITE OF EVENT
- K. STATE OF EVENT
- L. PROGRAM CODE (License Type)
- M. LICENSE NO. OF SITE
- N. WERE OTHER PARTIES INVOLVED?
IF SO, IDENTIFY (Provide
Name\City\State):
- O. RECIPROCITY (Code)
- P. REPORTABLE EVENT (Y\N):
NRC ☐ AS ☐
- Q. AEA (Y\N)
- R. ABNORMAL OCCURRENCE (Y\N)
- S. INVESTIGATION (Y\N)
- T. CONSULTANT (Y\N)
- U. TIME OF EVENT
- V. TIME ZONE
- W. EVENT DESCRIPTION (Code)
- X. CAUSE DESCRIPTION
- Y. CONTRIBUTING FACTOR (Code)
- Z. PRECIPITATING FACTOR (Code)
- AA. CORRECTIVE ACTION (Code)
- BB. REPORTING REQUIREMENT

- a. CLASS EVENT TYPE (Code)
- b. NRC 10 CFR (Code)
- c. AGREEMENT STATE
COMPATIBLE REGULATION

SPECIFIC INFORMATION BASED ON TYPE OF EVENT

1. RELEASE OF MATERIAL

(Where applicable).

- a. EVENT CLASS (Code)
- b. ISOTOPE (Code)
- c. ACTIVITY (Ci) (Code)
- d. CONSEQUENCE (Code)
- e. RADIONUCLIDE

2. MEDICAL EVENT INFORMATION (Where applicable)

ISOTOPE, ACTIVITY AND DOSAGE: (i.e., 10 mCi of Iodine-131;
40 rad of Cs-137; 200 μ Ci of Iodine Hippurate)

a. INTENDED DOSE (Code)

Millicuries
Radiopharmacy
Radionuclide

b. ACTUAL DOSE (Code)

Millicuries
Isotope
Chemical Form
Study\Procedure

- c. %OVERTREATMENT
- d. %UNDERTREATMENT
- e. CONSEQUENCES
- f. FAMILY DOSE (Rem)
- g. FETAL DOSE (Rem)
- h. DOSE NEWBORN (Rem)
- i. ORGAN (Code)
- j. EFFECT ON PATIENT(S)
- k. WHO ADMINISTERED
- l. DIAGNOSTIC OR THERAPEUTIC (D/T)
- m. TREATMENT PLAN AND SCHEDULE--INTENDED AND
ACTUAL (Include fractionations, where applicable)
- n. NO. OF PATIENTS
- o. PATIENT RESPONSIBLE RELATIVE NOTIFIED (Y\N)
- p. REFERRING PHYSICIAN NOTIFIED (Y\N)
- q. DEMOGRAPHICS

3. OVEREXPOSURE DATA (Where applicable)

- a. NO. OF PERSONS INVOLVED
- b. DOSE RECEIVED (rem)
- c. RADIATION SOURCE
- d. BODY PART RECEIVING DOSE

4. EQUIPMENT INFO. (Enter applicable data for all equipment in
use during event--hardware\software) Choose from code list for
a,b,c,d:

- a. SYSTEM ID #
- b. MANUFACTURER\SHIPPER
- c. MODEL NO.
- d. SERIAL\ID NO.
- e. MANUFACTURE DATE
- f. ISOTOPE ACTIVITY (Ci) (Code)
- g. ASSAY DATE
- h. SOURCE CHANGE DATE
- i. LEAK TEST RESULT (μ Ci)
- j. CONSEQUENCE

DATA ENTRY INFO. Cont.

5. ABSTRACT (Provide clear concise chronological statement in the form of a mini executive summary of the important facts concerning the event. This element is appended to as follow up information is added or when the licensee makes any corrections. It is not deleted and then rewritten as new information is obtained. Include direct cause, any new material, any retractions, licensee corrective actions, consultant statements, civil penalties, significant enforcement actions taken by State.)

January 21, 2000